DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
94370d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 3002186014

October 20, 2003

Erik S. Sowder, President
Brown Bag Lunch Co., Inc.
2901-A Research Park Drive
Soquel, California 95073

WARNING LETTER

Dear Mr. Sowder:

On September 2 and 4, 2003, we inspected your processing facility located at 2901-A Research Park Drive, Soquel, CA. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of 21 CFR Part 123, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your tuna sandwiches are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov. See the attached handout explaining how you can obtain a copy of the Fish & Fisheries Products Hazards and Controls Guidance, 3rd edition, June 2001.

The deviations observed were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan for tuna sandwiches to control the food safety hazard of pathogen growth, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for tuna sandwiches to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse.

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not

monitor the maintenance of hand-washing and hand-sanitizing facilities with sufficient frequency to ensure control, as evidenced by FDA observations that:

- the firm lacked effective hand-cleaning and hand-sanitizing preparations in the restrooms in the bakery and processing area, and
- the firm lacked a sanitary towel service or suitable hand-drying device in the restrooms in the bakery and processing area.

3. You must maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by 21 CFR 123.11(b) (discussed above), to comply with 21 CFR 123.11(c). However, your firm does not maintain the following sanitation monitoring records, which are required for the processing of tuna sandwiches to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse:

   - Safety of the water
   - Condition and cleanliness of food-contact surfaces
   - Prevention of cross-contamination
   - Maintenance of hand washing, hand sanitizing, and toilet facilities
   - Protection of food, food packaging material, and food contact surfaces from adulteration with contaminants
   - Proper labeling, storage, and use of toxic compounds
   - Control of employee health conditions that could result in microbiological contamination, and
   - Exclusion of pests from the facility.

In addition to the above-referenced violations, we note that the vegetable oil ingredient in your Breakfast Burrito must be declared in the ingredient statement for that product, pursuant to 21 CFR 101.4(b)(14).

At the conclusion of the inspection, the observed deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP Regulations, and the Current Good Manufacturing Practice Regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosures:

- Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001
- Form FDA 483